(107) *Cefpodoxime proxetil.* The term ''cefpodoxime proxetil working standard'' means a specific lot of a homogeneous preparation of cefpodoxime proxetil.

[39 FR 18925, May 30, 1974]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 430.5, see the List of CFR Sections Affected appearing in the Finding Aids section of this volume.

### § 430.6 Definitions of the terms "unit" and "microgram" as applied to antibiotic substances.

Unless it has been otherwise specified in the individual definitions in this section, the activity assigned to each ''unit'' or ''microgram'' is equivalent to an International Unit, if such has been defined by the World Health Organization.

(a) *''Unit''*—(1) *Penicillin*—(i) *Penicillin G.* The term ''unit'' applies to penicillin G means the penicillin activity (potency) contained in 0.600 microgram of the penicillin G master standard.

(ii) [Reserved]

(iii) *Penicillin V.* The term ''unit'' applied to penicillin V means the penicillin activity (potency) contained in 0.590 microgram of the penicillin V master standard.

(2) *Bacitracin.* The term ''unit'' applied to bacitracin means a bacitracin activity (potency) contained in 13.51 micrograms of the bacitracin master standard, except that when the activity (potency) of bacitracin is expressed in terms of its weight, as in the feed and drinking water of animals, 1 gram of activity is equivalent to 42,000 units.

(3) *Nystatin.* The term ''unit'' applied to nystatin means the nystatin activity (potency) contained in 0.2817 microgram of the nystatin master standard when dried for 2 hours at 40° C. and a pressure of 5 millimeters or less.

(4) *Polymyxin B.* The term ''unit'' applied to polymyxin B means the polymyxin activity (potency) contained in 0.1274 microgram of the polymyxin B master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(5) *Bleomycin.* The term ''unit'' applied to bleomycin means the bleomycin activity (potency) contained in 0.637 milligram of the bleomycin master standard.

(b) *''Microgram''*—(1) *Streptomycin.* The term ''microgram'' applied to streptomycin means the streptomycin activity (potency) contained in 1.250 micrograms of the streptomycin master standard after it is dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(2) *Dihydrostreptomycin.* The term ''microgram'' applied to dihydrostreptomycin means the dihydrostreptomycin activity (potency) contained in 1.25 micrograms of the dihydrostreptomycin master standard after it is dried for 4 hours at 100° C. and a pressure of 50 microns or less.

(3) *Chlortetracycline.* The term ''microgram'' applied to chlortetracycline means the chlortetracycline activity (potency) contained in 1.0 microgram of the chlortetracycline master standard.

(4) *Demeclocycline.* The term ''microgram'' applied to demeclocycline means the demeclocycline activity (potency) contained in 1.0 microgram of the demeclocycline master standard after it is dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(5) *Tetracycline.* The term ''microgram'' applied to tetracycline means the tetracycline activity (potency) contained in 1.0 microgram of tetracycline master standard.

(6) *Rolitetracycline.* The term ''microgram'' applied to rolitetracycline means the rolitetracycline activity (potency) contained in 1.0 microgram of the rolitetracycline master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(7) *Chloramphenicol.* The term ''microgram'' applied to chloramphenicol means the chloramphenicol activity (potency) contained in 1.0 microgram of the chloramphenicol master standard.

(8) *Methicillin.* The term ''microgram'' applied to methicillin means the methicillin activity (potency) contained in 1.105 micrograms of the methicillin master standard.

(9) *Oxacillin.* The term ''microgram'' applied to oxacillin means the oxacillin activity (potency) contained in 1.111

micrograms of the oxacillin master standard.

(10) [Reserved]

(11) *Amphotericin A.* The term ''microgram'' applied to amphotericin A means the amphotericin A activity (potency) contained in 1.0 microgram of the amphotericin A master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(12) *Amphotericin B.* The term ''microgram'' applied to amphotericin B means the amphotericin B activity (potency) contained in 1.014 micrograms of the amphotericin B master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(13) *Colistin.* The term ''microgram'' applied to colistin means the colistin base activity (potency) contained in 1.495 micrograms of the colistin master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less. The numerical value of a microgram of colistin is not equivalent to the International Unit.

(14) *Colistimethate.* The term ''microgram'' applied to colistimethate means the activity (potency) calculated as colistin base that is contained in 1.938 micrograms of the colistimethate master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less. The numerical value of a microgram of colistimethate is not equivalent to the International Unit.

(15) *Cycloserine.* The term ''microgram'' applied to cycloserine means the cycloserine activity (potency) contained in 1.0 microgram of the cycloserine master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(16) *Erythromycin.* The term ''microgram'' applied to erythromycin means the erythromycin base activity (potency) contained in 1.02 micrograms of the erythromycin master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(17) *Gramicidin.* The term ''microgram'' applied to gramicidin means the gramicidin activity (potency) contained in 1.0 microgram of the gramicidin master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(18) *Griseofulvin.* The term ''microgram'' applied to griseofulvin means the griseofulvin activity (potency) contained in 1.0 microgram of the griseofulvin master standard.

(19) *Kanamycin.* The term ''microgram'' applied to kanamycin means the kanamycin base activity (potency) contained in 1.299 micrograms of the kanamycin master standard.

(20) *Neomycin.* The term ''microgram'' applied to neomycin means the neomycin base activity (potency) contained in 1.429 micrograms of the neomycin master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(21) *Novobiocin.* The term ''microgram'' applied to novobiocin means the novobiocin acid activity (potency) contained in 1.033 micrograms of the novobiocin master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(22) *Oleandomycin.* The term ''microgram'' applied to oleandomycin means the oleandomycin base activity (potency) contained in 1.176 micrograms of the oleandomycin master standard.

(23) *Troleandomycin.* The term ''microgram'' applied to troleandomycin means the activity (potency), calculated as the molecular equivalent of the oleandomycin base, contained in 1.2315 micrograms of the troleandomycin master standard.

(24) *Oxytetracycline.* The ''microgram'' applied to oxytetracycline means the oxytetracycline base activity (potency) contained in 1.13 micrograms of the oxytetracycline master standard.

(25) *Paromomycin.* The term ''microgram'' applied to paromomycin means the paromomycin activity (potency) contained in 1.333 micrograms of the paromomycin master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(26) *Tyrothricin.* The term ''microgram'' applied to tyrothricin means the activity (potency) contained in 0.2 microgram of the gramicidin master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(27) *Vancomycin.* The term ''microgram'' applied to vancomycin means the vancomycin base activity (potency) contained in 1.25 micrograms of the vancomycin master standard.

(28) [Reserved]

(29) *Ampicillin.* The term ''microgram'' applied to ampicillin means the ampicillin activity (potency) contained in 1.1764 micrograms of the ampicillin master standard.

(30) *Nafcillin.* The term ''microgram'' applied to nafcillin means the nafcillin activity (potency) contained in 1.0989 micrograms of the nafcillin master standard.

(31) *Gentamicin.* The term ''microgram'' applied to gentamicin means the gentamicin activity (potency) contained in 1.56 micrograms of the gentamicin master standard when dried for 3 hours at 110° C. and a pressure of 5 millimeters or less.

(32) *Dactinomycin.* The term ''microgram'' applied to dactinomycin means the dactinomycin activity (potency) contained in 1.000 microgram of the dactinomycin master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(33) *Candicidin.* The term ''microgram'' applied to candicidin means the candicidin activity (potency) contained in 1.0 microgram of the candicidin master standard when dried for 3 hours at 40° C. and a pressure of 5 millimeters or less.

(34) *Cephalothin.* The term ''microgram'' applied to cephalothin means the cephalothin activity (potency) contained in 1.056 micrograms of the cephalothin master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(35) *Lincomycin.* The term ''microgram'' applied to lincomycin means the lincomycin base activity (potency) contained in 1.156 micrograms of the lincomycin master standard.

(36) *Cloxacillin.* The term ''microgram'' applied to cloxacillin means the cloxacillin activity (potency) contained in 1.135 micrograms of the cloxacillin master standard.

(37) *Methacycline.* The term ''microgram'' applied to methacycline means the methacycline activity (potency) contained in 1.082 micrograms of the methacycline master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(38) *Doxycycline.* The term ''microgram'' applied to doxycycline means the doxycycline activity (potency) contained in 1.155 micrograms of the doxycycline master standard.

(39) *Cephaloridine.* The term ''microgram'' applied to cephaloridine means the cephaloridine activity (potency) contained in 1.00806 micrograms of the cephaloridine master standard when dried for 3 hours at 60° C. and a pressure of 5 millimeters or less.

(40) *Dicloxacillin.* The term ''microgram'' applied to dicloxacillin means the dicloxacillin activity (potency) contained in 1.087 micrograms of the dicloxacillin master standard.

(41) *Plicamycin.* The term ''microgram'' applied to plicamycin means the plicamycin activity (potency) contained in 1.000 microgram of the plicamycin master standard when dried for 4 hours at 25° C. and a pressure of 5 millimeters or less.

(42) *Clindamycin.* The term ''microgram'' applied to clindamycin means the clindamycin activity (potency) contained in 1.139 micrograms of the clindamycin master standard.

(43) *Cephaloglycin.* The term ''microgram'' applied to cephaloglycin means the cephaloglycin activity (potency) contained in 1.02564 micrograms of the cephaloglycin master standard.

(44) *Carbenicillin.* The term ''microgram'' applied to carbenicillin means the carbenicillin activity (potency) contained in 1.135 micrograms of the carbenicillin master standard.

(45) *Cephalexin.* The term ''microgram'' applied to cephalexin means the cephalexin activity (potency) contained in 1.0707 micrograms of the cephalexin master standard.

(46) [Reserved]

(47) *Capreomycin.* The term ''microgram'' applied to capreomycin means the capreomycin activity (potency) contained in 1.0870 micrograms of the capreomycin master standard when dried for 4 hours at 100° C. and a pressure of 5 millimeters or less.

(48) *Rifampin.* The term ''microgram'' applied to rifampin means the rifampin activity (potency) contained in 1.0101

micrograms of the rifampin master standard.

(49) *Minocycline.* The term ''microgram'' applied to minocycline means the minocycline activity (potency) contained in 1.1588 micrograms of the minocycline master standard.

(50) *Spectinomycin.* The term ''microgram'' applied to spectinomycin means the spectinomycin activity (potency) contained in 1.490 micrograms of the spectinomycin master standard.

(51) *Clindamycin palmitate hydrochloride.* The term ''microgram'' applied to clindamycin palmitate hydrochloride means the clindamycin activity (potency) contained in 1.661 micrograms of the clindamycin palmitate hydrochloride master standard.

(52) *Carbenicillin indanyl.* The term ''microgram'' applied to carbenicillin indanyl means the carbenicillin activity (potency) contained in 1.4514 micrograms of the carbenicillin indanyl master standard.

(53) *Cephapirin.* The term ''microgram'' applied to cephapirin means the cephapirin activity (potency) contained in 1.0616 micrograms of the cephapirin master standard.

(54) *Cefazolin.* The term ''microgram'' applied to cefazolin means the cefazolin activity (potency) contained in 1.005 micrograms of the cefazolin master standard.

(55) *Mitomycin.* The term ''microgram'' applied to mitomycin means the mitomycin activity (potency) contained in 1.0416 micrograms of the mitomycin master standard.

(56) *Amoxicillin.* The term ''microgram'' applied to amoxicillin means the amoxicillin activity (potency) contained in 1.17647 micrograms of the amoxicillin master standard.

(57) [Reserved]

(58) *Cephradine.* The term ''microgram'' applied to cephradine means the cephradine activity (potency) contained in 1.1111 micrograms of the cephradine master standard.

(59) *Doxorubicin.* The term ''microgram'' applied to doxorubicin means the activity (potency) calculated as doxorubicin hydrochloride contained in 1.0204 micrograms of the doxorubicin master standard.

(60) *Tobramycin.* The term ''microgram'' applied to tobramycin means the tobramycin activity (potency) contained in 1.126 micrograms of the tobramycin master standard.

(61) *Amikacin.* The term ''microgram'' applied to amikacin means the amikacin activity (potency) contained in 1.091 micrograms of the amikacin master standard.

(62) *Vidarabine.* The term ''microgram'' applied to vidarabine means the vidarabine activity (potency) contained in 1.0674 micrograms of the vidarabine master standard.

(63) *Ticarcillin.* The term ''microgram'' applied to ticarcillin means the ticarcillin activity (potency) contained in 1.136 micrograms of the ticarcillin master standard.

(64) *Cefadroxil.* The term ''microgram'' applied to cefadroxil means the cefadroxil activity (potency) contained in 1.0537 micrograms of the cefadroxil master standard.

(65) *Natamycin.* The term ''microgram'' applied to natamycin means the natamycin activity (potency) contained in 1.0846 micrograms of the natamycin master standard.

(66) *Cefoxitin.* The term ''microgram'' applied to cefoxitin means the cefoxitin activity (potency) contained in 1.072 micrograms of the cefoxitin master standard.

(67) *Cefamandole.* The term ''microgram'' applied to cefamandole means the cefamandole activity (potency) contained in 1.1364 micrograms of cefamandole master standard.

(68) *Cefaclor.* The term ''microgram'' applied to cefaclor means the cefaclor activity (potency) contained in 1.0493 micrograms of cefaclor master standard.

(69) *Cyclacillin.* The term ''microgram'' applied to cyclacillin means the cyclacillin activity (potency) contained in 1.01 micrograms of the cyclacillin master standard.

(70) *Daunorubicin.* The term ''microgram'' applied to daunorubicin means the daunorubicin activity (potency) contained in 1.0965 micrograms of the daunorubicin master standard.

(71) *Sisomicin.* The term ''microgram'' applied to sisomicin means the sisomicin activity (potency) contained

in 1.00 microgram of the sisomicin master standard expressed on an anhydrous basis.

(72) *Meclocycline.* The term ''microgram'' applied to meclocycline means the meclocycline activity (potency) contained in 1.0493 micrograms of the meclocycline master standard.

(73) *Cefotaxime.* The term ''microgram'' applied to cefotaxime means the cefotaxime activity (potency) contained in 1.089 micrograms of cefotaxime master standard.

(74) *Mezlocillin.* The term ''microgram'' applied to mezlocillin means the mezlocillin activity (potency) contained in 1.1086 micrograms of the mezlocillin master standard.

(75) *Moxalactam.* The term ''microgram'' applied to moxalactam means the moxalactam activity (potency) contained in 1.1173 micrograms of the moxalactam master standard.

(76) *Piperacillin.* The term ''microgram'' applied to piperacillin means the piperacillin activity (potency) contained in 1.0460 micrograms of the piperacillin master standard.

(77) *Cefoperazone.* The term ''microgram'' applied to cefoperazone means the cefoperazone activity (potency) contained in 1.056 micrograms of the cefoperazone master standard.

(78) *Azlocillin.* The term ''microgram'' applied to azlocillin means the azlocillin activity (potency) contained in 1.128 micrograms of the azlocillin master standard.

(79) *Netilmicin.* The term ''microgram'' applied to netilmicin means the netilmicin activity (potency) contained in 1.000 microgram of the netilmicin master standard expressed on an anhydrous basis.

(80) *Cefuroxime.* The term ''microgram'' applied to cefuroxime means the cefuroxime activity (potency) contained in 1.0893 micrograms of the cefuroxime master standard.

(81) *Ceftizoxime.* The term ''microgram'' applied to ceftizoxime means the ceftizoxime activity (potency) contained in 1.011 micrograms of the ceftizoxime master standard.

(82) *Cyclosporine.* The term ''microgram'' applied to cyclosporine means the cyclosporine activity (potency) contained in 1.0173 micrograms of cyclosporine master standard.

(83) *Ceforanide.* The term ''microgram'' applied to ceforanide means the ceforanide activity (potency) contained in 1.005 micrograms of the ceforanide master standard.

(84) *Cefonicid.* The term ''microgram'' applied to cefonicid means the cefonicid activity (potency) contained in 1.150 micrograms of the cefonicid master standard.

(85) *Clavulanic acid.* The term ''microgram'' applied to clavulanic acid means the clavulanic acid activity (potency) contained in 1.053 micrograms of clavulanic acid master standard.

(86) *Amdinocillin.* The term ''microgram'' applied to amdinocillin means the amdinocillin activity (potency) contained in 1.004 micrograms of the amdinocillin master standard.

(87) *Ceftriaxone.* The term ''microgram'' applied to ceftriaxone means the ceftriaxone activity (potency) contained in 1.19 micrograms of the ceftriaxone master standard.

(88) *Ceftazidime.* The term ''microgram'' applied to ceftazidime means the ceftazidime activity (potency) contained in 1.1834 micrograms of the ceftazidime master standard.

(89) *Imipenem.* The term ''microgram'' applied to imipenem monohydrate means the imipenem activity (potency) contained in 1.085 micrograms of the imipenem master standard.

(90) *Cefotetan.* The term ''microgram'' applied to cefotetan means the cefotetan activity (potency) contained in 1.012 micrograms of the cefotetan master standard.

(91) *Aztreonam.* The term ''microgram'' applied to aztreonam means the aztreonam activity (potency) contained in 1.05 micrograms of the aztreonam master standard.

(92) *Sulbactam.* The term ''microgram'' applied to sulbactam means the sulbactam activity (potency) contained in 1.002 micrograms of the sulbactam master standard.

(93) *Cefuroxime axetil.* The term ''microgram'' applied to cefuroxime axetil means the cefuroxime activity (potency) contained in 1.246 micrograms of the cefuroxime axetil master standard.

(94) *Cefmenoxime.* The term ''microgram'' applied to cefmenoxime

means the cefmenoxime activity (potency) contained in 1.0482 micrograms of the cefmenoxime master standard.

(95) *Cefixime.* The term ''microgram'' applied to cefixime means the cefixime activity (potency) contained in 1.126 micrograms of the cefixime master standard.

(96) *Cefotiam.* The term ''microgram'' applied to cefotiam means the cefotiam (potency) contained in 1.144 micrograms of the cefotiam master standard.

(97) *Clindamycin phosphate.* The term ''microgram'' applied to clindamycin phosphate means the clindamycin phosphate (potency) contained in 1.252 micrograms of the clindamycin phosphate master standard.

(98) *Mupirocin.* The term ''microgram'' applied to mupirocin means the activity (potency) calculated as mupirocin activity (potency) contained in 1.075 micrograms of the mupirocin master standard.

(99) *Cefmetazole.* The term ''microgram'' applied to cefmetazole means the cefmetazole (potency) contained in 1.002 micrograms of the cefmetazole master standard.

(100) *Cefpiramide.* The term ''microgram'' applied to cefpiramide means the cefpiramide (potency) contained in 0.994 microgram of the cefpiramide master standard.

(101) *Clarithromycin.* The term ''microgram'' applied to clarithromycin means the clarithromycin (potency) contained in 1.010 micrograms of the clarithromycin master standard.

(102) *Azithromycin.* The term ''microgram'' applied to azithromycin means the azithromycin (potency) contained in 1.063 micrograms of the azithromycin master standard.

(103) *Cefprozil.* The term ''microgram'' applied to cefprozil (Z) means the cefprozil (Z) potency contained in 1.060 micrograms of the cefprozil (Z) master standard. The term ''microgram'' applied to cefprozil (E) means the cefprozil (E) potency contained in 1.106 micrograms of the cefprozil (E) master standard.

(104) *Idarubicin.* The term ''microgram'' applied to idarubicin means the idarubicin activity (potency) calculated as idarubicin hydrochloride contained in 1.036 micrograms of the idarubicin master standard.

(105) *Loracarbef.* The term ''microgram'' applied to loracarbef means the loracarbef (potency) contained in 1.059 micrograms of the loracarbef master standard.

(106) *Rifabutin.* The term ''microgram'' applied to rifabutin means the rifabutin (potency) contained in 1.022 micrograms of the rifabutin master standard.

(107) *Cefpodoxime proxetil.* The term ''microgram'' applied to cefpodoxime proxetil means the cefpodoxime (potency) contained in 1.304 micrograms of the cefpodoxime proxetil master standard when dried.

[39 FR 18925, May 30, 1974]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 430.6, see the List of CFR Sections Affected appearing in the Finding Aids section of this volume.

## Subpart B—Antibiotic Drugs Affected by the Drug Amendments of 1962

### § 430.10 Certification or release of antibiotic drugs affected by the drug amendments of 1962.

(a) Before the 1962 amendments to it, the Federal Food, Drug, and Cosmetic Act only permitted the Food and Drug Administration to provide for the certification of batches of antibiotic drugs containing penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or any derivative of them. FDA certified those drugs under regulations promulgated on the basis of scientific proof of the drugs' safety and effectiveness. Most drugs containing an antibiotic other than one of those listed were subject to the new drug provisions of the act, which required that an applicant show that the drug was safe and obtain FDA approval of a new drug application before marketing it. An affirmative showing of effectiveness was not then required to obtain approval. Some antibiotic drugs that were not subject to certification, however, were also not subject to the new drug provisions of the act under informal FDA opinions that the drug was ''not a new drug'' or ''no longer a new drug.'' FDA